Cheetah Medical

Cheetah Medical, Inc
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201
USA

K103166 1/3

JAN 25 2011

510(k) Summary

Submitter: Cheetah Medical, Inc.
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201

Contact Person:
Rhona Shanker
Regulatory Consultant to
Cheetah Medical, Inc.
Ph: (301) 251-9570
Fax: (301) 251-9571

Device: Trade Name:
Cheetah Reliant
Common/Usual Name
Portable, non-invasive Cardiac Output and hemodynamic monitoring device
Non-invasive blood pressure monitor
Non-invasive blood oxygen saturation monitor
Classification Name:
21 CFR 870.2770/DSB – Impedance plethysmograph
21 CFR 870.1130/DXN – Non-invasive blood pressure monitor
21 CFR 870.2700/DQA- Non-invasive blood oxygen saturation monitor

Predicate Devices:
K083093 - Cheetah Reliant with NIBP functionality
K060576 - NELLCOR /N-600x Oximax pulse oximeter

Device Description:
The Cheetah Reliant with oxygen saturation (SpO2) function is a modification of the Cheetah Reliant device cleared under K083093. The significant modification is the addition of a non invasive Oxygen Saturation (SpO2) module to the system which involved updating the user interface to allow operating the SpO2 module and for displaying the results and saving them within the device's database.

The SpO2 Module is the NELLCOR OxiMax NELL-1 Pulse Oximetry Module, manufactured by NELLCOR Pleasanton, CA ,USA, a division of Covidien. It is the same module that is in the NELLCOR OxiMax N-600x Pulse Oximeter (K060576).

Cheetah Medical

Cheetah Medical, Inc
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201
USA

The NELL-1 pulse oximeter board that is integrated into the Cheetah Reliant, uses calibration data contained in the OxiMax pulse oximetry sensor when calculating the patient's SpO2.

The NELL-1 Module connects to a OxiMax pulse oximetry sensor (DS-100A Durasensor®, the same sensor cleared with the OxiMax N-600x, K060576), through a Pulse Oximetry Cable (NELLCOR, DOC-10) that was also cleared with the OxiMax N-600x Pulse Oximeter (K060576) and provides oscillometric oxygen saturation to the Host system. The Module is controlled via software commands issued from the Host system through an asynchronous serial data port. All Module operations are initiated by the Reliant as the Host system. The Module is designed to take blood oxygen saturation measurements on demand.

Indications for Use:

The Cheetah Reliant with NIBP and SpO2 functionalities is a portable, hemodynamic monitoring non-invasive Cardiac Output monitoring device that monitors and displays a patient' Cardiac Output (CO) in Ltr/Min with a Non Invasive Blood Pressure (NIBP) function that non-invasively measures and displays blood pressure (diastolic, systolic and mean arterial pressure) and heart rate and with a SpO2 function that non-invasively measures and displays blood oxygen saturation (SpO2). The device displays associated heamodynamic parameters based on calculations with measurements already incorporated into the Cheetah Reliant. These parameters are:

- Cardiac Index (CI),
- Stroke Volume (SV),
- Stroke Volume Index (SVI),
- Stroke Volume Variation (SVV),
- Heart Rate (HR),
- Ventricular Ejection Time (VET),
- Total Peripheral Resistance (TPR),
- Total Peripheral Resistance Index (TPRI),
- Cardiac Power (CP),
- Cardiac Power Index (CPI),
- Oxygen Delivery Index (DO2I),
- Electrical impedance of the chest cavity (Z0),
- Thoracic Fluid Content (TFC),
- Thoracic Fluid Content change from preset time period (TFC*d*) and
- Thoracic Fluid Content from baseline (TFC*d0*).
- Orthostatic Bioreactance (Postural changes in SV, CO and other hemodynamic parameters which are derived by Bioreactance)

The Cheetah Reliant with NIBP and SpO2 functionalities is intended for use within hospitals and other healthcare facilities (e.g., outpatient clinics) that provide patient care.

Cheetah Medical

Cheetah Medical, Inc
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201
USA

K103166 3/3

The revised "indications for use" includes the SpO2 functionality and Orthostatic Bioreactance. Orthostatic Bioreactance will display the changes in SV, CO and other hemodynamic parameters displayed by the Reliant, as a result of changes in posture.

Comparison to Predicates

The Cheetah Reliant with NIBP and SpO2 functionalities is substantially equivalent to the following:

- Cheetah Reliant with NIBP functionality (K083093).
- NELLCOR OxiMax N-600x Pulse Oximeter (K060576) for the SpO2 function

Test Summary:

The following assessments were conducted to verify performance:

- Software verification and validation
- Electrical Safety
- EMC
- Performance testing to verify that SpO2 values calculated by the OEM SpO2 module are not corrupted during communication with the Reliant (i.e., verified that calculated and displayed values are identical)

Conclusion:

The Cheetah Reliant with NIBP and SpO2 functionality is substantially equivalent to the identified predicate devices as it has the same indications for use, incorporates the same fundamental scientific technologies as the predicates, contains the same SpO2 OEM parts (module, cable and sensor) as the cleared SpO2 predicate, and testing demonstrates that its performance is substantially equivalent. As such, the Cheetah Reliant with NIBP and SpO2 functionality is safe and effective for use as described in the indications for use statement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cheetah Medical, Inc.
c/o Ms. Rhona Shanker
Consultant
Z&B Enterprises, Inc.
12154 Darnestown Road # 236
Gaithersburg, MD 20878

JAN 25 2011

Re: K103166
Trade/Device Name: Cheetah Reliant with NIBP and SpO2
Regulation Number: 21 CFR 870.2270
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB, DXN, DQA
Dated: October 26, 2010
Received: October 27, 2010

Dear Ms. Shanker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. C. Kellerman

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K103166

Device Name: **Cheetah Reliant**

Indications for Use:

The Cheetah Reliant with NIBP and SpO2 functionalities is a portable, hemodynamic monitoring and non-invasive Cardiac Output monitoring device that monitors and displays a patient' Cardiac Output (CO) in Ltr/Min with a Non Invasive Blood Pressure (NIBP) function that non-invasively measures and displays blood pressure (diastolic, systolic and mean arterial pressure) and heart rate and with a SpO2 function that non-invasively measures and displays blood oxygen saturation (SpO2). The device displays associated heamodynamic parameters based on calculations with measurements incorporated into the Cheetah Reliant. These parameters are:

- Cardiac Index (CI),
- Stroke Volume (SV),
- Stroke Volume Index (SVI),
- Stroke Volume Variation (SVV),
- Heart Rate (HR),
- Ventricular Ejection Time (VET),
- Total Peripheral Resistance (TPR),
- Total Peripheral Resistance Index (TPRI),
- Cardiac Power (CP),
- Cardiac Power Index (CPI),
- Oxygen Delivery Index (DO2I),
- Electrical impedance of the chest cavity (Z0),
- Thoracic Fluid Content (TFC),
- Thoracic Fluid Content change from preset time period (TFC*d*) and
- Thoracic Fluid Content from baseline (TFC*d0*).
- Orthostatic Bioreactance (Postural changes in SV, CO and other hemodynamic parameters which are derived by Bioreactance)

The Cheetah Reliant with NIBP and SpO2 functionalities is intended for use within hospitals and other healthcare facilities (e.g., outpatient clinics) that provide patient care.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

M. A. Villarreal

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

510(k) Number K103166